Section 4, Remarks:

Reexamination and reconsideration of this case is respectfully requested in view of the foregoing amendments to the claims and these Remarks. Please note this case is SPECIAL

Applicant expresses appreciation for the Telephone Interview and the substantial progress made in the prosecution of the case. Pursuant to the gracious offer of SPE Low, Applicant has requested a follow-up Telephone Interview with the Examiner to determine any remaining open issues that, hopefully, can be resolved by Examiner Amendment.

20 claims are in this case. The Restriction and Election of Species requirements are traversed and Applicant respectfully requests they be reconsidered and withdrawn. Currently, Claims 1 – 15 are being examined. Applicant requests examination of all 20 claims.

Applicant has been advised in the Telephone Interview of March 27 that the new Declaration has been accepted and entered, so the requirement on pages 4 and 5 of the Office Action have been satisfied and are now moot.

In addition, the Objection to the Specification has been satisfied by the amendment to the Specification in Section 2, above.

Amendments to Claims; No New Matter Has Been Added:

Claims 1, 3, 6, 7, 10, 12, 14, 16, 19 and 20 have been amended to more clearly point out and distinctly claim the inventive targeted delivery system platform and the method of targeted treatment using that unique platform.

Main claims 1, 10 and 16 have been amended to introduce the requested "consisting essentially of" language to clarify that tooth brushing and compositions such as in Kazdan are outside the scope of the claims. See Claim 1, line 2; Claim 10, line 5 and claim 16, line 3. This is consistent with the invention as described in the Specification considered as a whole, from which it is clear that the invention is directed to treatment of bad breath and gingivitis by topical application of anti-bacterial solutions to soft oral tissue and the gingival sulcus. The action of the buccinator muscle promotes massaging of the gum tissue by the rolls to stimulate parotid saliva production, thereby increasing the natural bactericidal lysozyme and rinsing activity of saliva.

Main Claims 1 and 10 have been amended in part c), and Main Claim 16 in part b) to more clearly recite the insertion of the medicated rolls in the buccal vestibules for an extend-ed period of time and upon action of the buccinator muscles for the expression and subsequent leaching of the treatment composition and stimulation of parotid saliva to effect treatment. This is extensively set forth in the Specification as filed, see, e.g., page 2, line 23 through page 3, line 14 and page 8, line 27 through page 9, line 1.

In addition, the disposability of the single-use rolls, carrying single use dosages of the topical oral medication has been emphasized by the amendments in parts a) and b) of Claims 1 and 10, and in step a) of Claim 16. With respect to terms, the following shows examples of support in the text of the Specification; see also The Figures:

Leaching	Original Claim 16, step c)
Oral tissue	Original Claim 16, step c)
Sulcus	Page 3, line 27 and throughout
Free margin sulcus recess	Page 3, line 4
Space between teeth	Page 2, line 27
Extended periods	Page 2, line 29; page 5, line 28
Platform for delivery of topical oral medication	Page 2, lines 33 – 34
Buccinator muscle action	Page 3, lines 3 – 6
Medication aliquot	Page 11, lines 8 – 14
Single use disposable dosage	Page 1, lines 11 – 12
Bathes oral cavity & tongue	Page 8, lines 33 and 34
Laves	Page 8, line 31
Gums, sulcus & teeth	Page 8, lines 31 and 32
Dosage amounts	Page 12, line 9.

Claim 3, line 5 was corrected for the proper antecedent it being the word "composition", see line 2. Claims 7, 14 and 20 were amended to insert the term "about" in reference to the dimensions, to make the claims consistent with the Specification and Original Claims as filed. Note applicant responds to the 112 rejection of that term below. It is self-evident to those skilled in the art that the dimensions of the cotton rolls are not critical, Applicant would be pleased to amend the claims to read "on the order of" instead of "about," if the Examiner considers that more suitable. The grammar of Claim 12 has been amended so that it is clear the seal includes a zip-type closure structure as well as the tear-off strip; see Fig. 3, elements 12 and 20.

Claims 6 and 19 have been amended to remove potentially objectionable terms "such as" and "and the like" from the Markush listing of compositions.

It is clear that no new matter has been added, the amendatory language being extensively supported throughout the Specification, the Original Claims as filed and the Drawings. Entry of the amendments to the Specification is requested.

Response to the §112 Indefiniteness Rejection of Claims 7, 9 and 14:

This rejection is inappropriate and unnecessary. In the Telephone Interview of March 27, SPE Low stated that this issue was under consideration. Accordingly, Applicant repeats here the remarks earlier presented on February 16, 2006 for the convenience of the Examiner in her review.

The rejected claims are dependent claims. The claims are directed to one skilled in this art. It is clear from the Specification that the measurements need not be precise. Thus, one

skilled in the art would not consider that there is anything indefinite or unclear about these non-critical measurements. The Specification clearly states that the inventive medicated rolls are meant for the range of sizes of the buccal vestibules of infants, children and adults. It is well within the skill of those in the art, such as Dr. Novotny, to adjust the measurements of length and diameter to be most comfortable in use. The Examiner is requested to show case law that all usages of the term "about" or "from about" are forbidden in patent claims. Applicant would be pleased to provide a declaration from Dr. Novotny, as one skilled in the art, that the terms are not indefinite or unclear. Please advise if that would satisfy the concern.

If the Examiner would feel more comfortable, Applicant would be pleased to substitute the term "on the order of" for the term "about". See the Specification at, for example, page 3, line 17.

The PTO and Courts are more discriminating and rational about the terms "about" and "from about." So as to not burden the record, Applicant cites here only a few of many instances in which Courts have **approved** the PTO's allowance of claims using the terms "about" and "from about" in claims. **These are instances tested in the heat of inter-parties battle**, not merely ***ex parte*** review on a theoretical stage. The Examiner is invited to review ***Zoltek v. United States***, 57 USPQ 2nd 1257 (US Ct Fed. Claims, 2000), wherein the United States **lost** the argument that use of the term "about" was indefinite. In ***Zoltek*** the Court stated (opinion, pg 10):

> The Court concludes that the term "about 1300 degrees Centigrade" when read in light of the specification is sufficiently clear to apprise a person skilled in the art of the scope of the invention. Thus, the Court rejects Defendant's contention that the **term "about** 1300 degrees Centigrade" is **indefinite.**
>
> . . . Whether a claim is **indefinite** under ***35 U.S.C. Section 112,*** Para. 2 is a question of law. ***Personalized Media LLC v. Int'l Trade Comm , 161 F.3d 696, 702-03, 48 USPQ2d 1880, 1886 (Fed. Cir. 1998)*** **(citing** ***North Am. Vaccine, Inc. v. American Cyanamid Co. , 7 F.3d 1571, 1579, 28 USPQ2d 1333, 1339 (Fed. Cir. 1993)).*** "A determination of claim indefiniteness is a legal conclusion that is drawn from the court's performance of its duty as the construer of patent claims." ***Personalized Media , 161 F.3d at 705.*** "The test for definiteness is whether one skilled in the art would understand the bounds of the claim when read in light of the specification. If the claims read in light of the specification reasonably apprise those skilled in the art of the scope of the invention, Section 112 demands no more." ***Miles Lab., Inc. v. Shandon, Inc. , 997 F.2d 870, 875, 27 USPQ2d 1123, 1126 (Fed. Cir. 1993)*** (internal citations omitted).

The ***Zoltek*** Court also noted that the CAFC stated in ***Amgen, Inc. v Chugai Pharmaceutical Co., Ltd***, 927 F3rd 1200 (CAFC 1991) that its ruling therein did ***NOT*** preclude that the future use of the term "about" in claims would be unacceptable, ***Amgen*** 927 F. 3d at 1217. Since the US lost the ***Zoltek*** case, wherein it argued the patent was invalid for indefiniteness, the action of the US PTO Examiner who permitted the use of the term "about" in the Zoltek patent claims was appropriate. **This is proof that "about" is deemed entirely proper by USPTO Examiners.**

To similar effect, the US District Court for Delaware held in ***CPC International Inc. v.***

Archer Daniels Midland Co., 30 USPQ 2nd 1427, that a value of 616cm/sec was within the claims of the patent which call for speeds of "from about 60 cm/sec. to about 600 cm/sec", opinion page 14 (the patent was held not infringed on other grounds). **Thus, again the PTO Examiner allowed the terms "about" and "from about", and he/she was correct.**

In ***Eiselstein v. Frank***, 34 USPQ 2nd 1467 (CAFC 1955), the Court resolved the issue, in an interference (an inter-parties matter), that the use of the term "about" in claims in a grand-daughter application did **NOT** constitute a change to a distinct and different invention from that disclosed in the grand-parent, priority case, because the claims were now indefinite due to use of "about." The Court ruled, ***as a matter of law*** (opinion page 7):

> The meaning of the word "about" is dependent on the facts of a case, the nature of the invention, and the knowledge imparted by the totality of the earlier disclosure to those skilled in the art. See *In re Wertheim , 541 F.2d at 262, 191 USPQ at 96* . . . .
> In this case, it was clear error to find that a person skilled in the art would not have considered the grandparent application to describe an approximate range of nickel. The later use of the term "about" to describe the range of nickel did not constitute a change to a distinct and different invention. Since the finding of the board concerning the disclosure of the grandparent application was clearly erroneous, the rejection of claims 8-18 based on that error was perforce erroneous as a matter of law.

Accordingly, it is Applicant's position that the terms "about" and "from about" are not unclear or indefinite within the totality of the disclosure, when used in dependent claims, and as considered by those skilled in this art. This view is supported by thousands of Examiners (of which undersigned Counsel was once one), tested in extensive inter-parties contests, and approved by federal courts, including the CAFC, whose decisions are binding on the USPTO. It is appropriate to withdraw the rejection.

Response to the §102 Rejection of Claims 1 – 4 and 7 over Kazdan '382:

This rejection is inappropriate as Kazdan is directed to a tooth cleaning device, a cotton pad that is coated with dentifrice made of a mixture of pumice and sugar (saccharide). It is used to scrub the teeth. There is no disclosure to use the Kazdan handle-less toothbrush (it is not clear but we suppose one is to hold the roll of Fig. 3 between the thumb and first finger and scrub the teeth with the exposed end) in the manner recited in the claims, and the claims exclude the Kazdan pumice by the amendatory language "consisting essentially of".

The rejection seems to have been fuelled by an overbroad misreading of the claims, which it is understood is resolved by the "consisting essentially of" language. Applicant understands from the Telephone Interview that upon insertion of that language in main claims 1, 10 and 16, "Kazdan goes away".

Thus, the Office Action rejection, in referring to the original claims, repeatedly states that Kazdan is "considered to meet Applicant's limitation of (whatever the Examiner cannot find in

the reference)". Tooth scrubbing, tooth brushing, tooth rubbing is not within the meaning of "oral hygiene" as defined in the main claims 1, 10 and 16. To insure clarity, Applicant has excluded the Kazdan tooth cleaning compositions from the oral soft tissue hygiene device and methods claimed. The amendments make it clear that the inventive medicated roll is inserted in the buccal vestibule, which is not scrubbing teeth as in Kazdan. Futher, the interaction with the buccinator muscle to express the medication from the roll, not pressing on the teeth with a finger as in Kazdan, clearly spells out the patentable distinction.

The Examiner is requested to provide evidence that the Kazdan "cleansing additives" (Examiner's language) are the anti-microbial components of applicant's medications. Note that Kazdan discloses "an abrasive tooth cleaning composition containing a major portion of pumice and including from about ***[Oops, there are those evil words again, in a reference's claim no less, see Kazdan's claim 1]*** 0.1% to about 10% by weight based on the weight of the fibrous body [not specified] of a water-soluble saccharide binding agent". That composition is nowhere taught in either Kazdan or in Applicant's Specification to be the claimed "topical oral medications". The only liquid in Kazdan is a transitory way to get the toothpaste in and on the Kazdan cotton pad. They are then dried.

Clearly, the Examiner is relying on phantom art to teach an equivalence, and glosses over that by saying Kazdan's dentifrice is "***considered*** by the Examiner ***to include*** the disclosed bactericidal component", **as if the Examiner's mere deeming something to be so makes it so**. Technically, Applicant challenges the Examiner to show that pumice and saccharide (an alternate name for sugar) are bactericidal. In fact, saccharide in Kazdan appears used as a sweetner, and as such would be food for bacteria, not a bactericide. ***In any event, the Examiner's unsupported opinion as basis for any rejection is not the law.***

Consider what the law really is: The Board of Patent Appeals and Interferences does not condone that approach, stating in ***Ex parte Stern,*** **13 USPQ 2d 1379 at 1381:**

> "The examiner should be aware that "deeming" **does not discharge him [or her] from the burden of providing the requisite factual basis and establishing the requisite motivation to support a conclusion of obviousness.** [Citing cases] The examiner's reference to unidentified phantom prior art techniques falls far short of the mark. [Citing cases] **Accordingly, the examiner's rejection** of the appealed claims under 35 USC 103 as unpatentable over any of the primary references, considered singly, **is reversed.**"

While that case spoke to a 103 rejection, it applies no less to misconstruing a reference in an attempt to create a 102 rejection. Blatantly evident misrepresentations of the references are not support for the rejections. The Examiner merely stating that he/she "considers" a very different

term in the reference to be a term in the claim does not discharge the Examiner's burden of presenting factual evidence.

Quite clearly the Kazdan reference does not show the claimed medications introduced into a roll for the functionality claimed. The claim limitations, brushed off by the rejections as being directed to a "mere" intended use are far more; they are statements of functions of the combination that are not taught (nor suggested) in Kazdan. It is entirely appropriate to consider the elements of a combination in their context of use. If that were not the case, then every mechanical device would be rejectable over a bag of parts, all of which are standard nuts, bolts, plates, springs, bearings, belts, etc. The point is clear: The Office cannot ignore 99% of the claim and then say, well, then, the remaining 1% is well known. To show how wrong that is, Kazdan should have been rejected over sticking your finger in tooth powder and rubbing your teeth, both well known for a hundred years before Kazdan filed.

The rejection reflects a disrespect for the inventive contribution: A delivery platform for targeted delivery, in lesser but more effective amounts than popular mouthwash or toothbrushing (whether with a brush or your fingertip as in Kazdan), for serious oral conditions such as halitosis, ANUG and gingivitis.

The rejection is obviously unsound and should be withdrawn.

Response to the §103 Rejection of Claims 1-4 and 6-15 over 6 References:

Applicant assumes this rejection would apply to claims 16 – 20 as well. The secondary references do not cure the defects in Kazdan that the Examiner points out on page 10 of the Detailed Action. The rejection is unsound and should be withdrawn.

It is noted, not without some recognition of the obvious inconsistency with the 102 rejection, that in this 103 rejection of claims 1 – 4, Kazdan needs a lot of help. But 5 different references, no less? None more pertinent, no less! And none of them, taken alone or in combination teach the inventive contribution of a simple, portable, disposable, single use, single dose of topical oral medication delivered in a targeted functionality by the medicated cotton rolls claimed.

Weisel is directed to white strips. No teaching of buccal vestibular use, shape, functionality. This is another tooth care reference. What it teaches in combination with Kazdan is that the Kazdan pumice/sugar composition could be put on Weisel's strips; OR that the Weisel's whitner could be put on Kazdan"s pads. Neither is the claimed invention.

Vermeer is directed to an alkyl aldonamide compound-containing composition. It does not cure the defects of Kazdan. Note it distinguishes between dentifrices and mouthwashes, see

columns 1 – 3. Nowhere does it suggest the combination with Kazdan's pumice/sugar dentifrice impregnated finger-manipulated tooth scrubbing pads. At best, with hindsight one might use the Vermeer aldonamide compound in place of the Kazdan sugar as a binder, but even if it did, Applicant's invention is not directed to tooth cleaning. Vermeer suggests use in a mouthwash, but Applicant's invention is not a mouthwash. Again, the Office fails to address the delivery platform nature of the inventive combination.

Julius shows a dental sponge. What is the combination with Kazdan? Substitute the Julius double-V-grooved sponge for the Kazdan finger pad? But that is not the invention.

Speaker is directed to a delivery system for topical applications comprising, not a cotton roll, but a highly viscous carrier containing dissolved or dispersed topically-active agents that are microencapsulated for sustained release. He mentions in passing **"very elaborate and somewhat uncomfortable methods of treatment"** of gingivitis, namely "**implanting in the periodontal sulcus one or more coils of an anitibiotic-impregnated cotton or nylon braided cord**". Clearly a roll is not a cord, and the claimed rolls are not "coils of braided cord". More importantly, they are inserted in the buccal vestibules, not IMPLANTED surgically in the periodontal sulcus. It should be noted that the treatment referred-to is a surgical procedure directed to periodontitis, not gingivitis. The reference to "periodontal sulcus" indicates a pathologic condition, 3 – 5 mm deep detachment of the tissue from the teeth and jawbone accompanied by bone loss, and not something effectively treated by mouthwash.

Copelan is directed to what appears to be a floss holder or a tongue brush, or both. Again this reference is directed to teeth, not the application-specific combination claimed. Clearly Copelan is not resealable, and not pocket sized. Its relevance is not clear.

The rejection repeatedly refers to one teaching or another, always of course one that is missing from the references, as being "prima facie obvious to the skilled artisan"; see pages 11, 12, 13 and 14 (indeed, in conjunction with ***every*** rejection). In another astonishing instance, the rejection states (page 13) that "the use of ***any*** packaging ***known in the art*** would have been ***plainly obvious*** [not just "obvious", but "plainly obvious"] to the skilled artisan." The same inappropriate "plainly obvious" language is used on page 11. ***Moreover, as to that quote on page 13, the packaging allegedly "known in the art" is not revealed to Applicant, so it is impossible to refute the unsupported, broad brush (off) of the invention. That's a denial of substantive due process.***

In addition, the rejection states at page 13 that "motivation to employ such a type of cotton formulation ***flows logically from the desire*** to enhance absorbency of the composition

and/or to sustain localized topical drug delivery by serving as a reservoir providing the active agent(s)." That "flows logically" language is repeated on pages 11 and 12. The mere fact that something existed in the prior art, assuming arguendo that it did, does not provide motivation. **That is, existence of a part is not motivation for a combination; the Examiner is requested to cite a CAFC case that says it is (not *ex cathedra* MPEP language, or the Examiner's "deeming" something obvious).**

There is so much wrong with the above-referenced thinking in the Office Action that it is hard to know where to begin. Lets start with the principles of law applying to obviousness rejections. In essence the rejections are trying to state the claims are obvious in the absence of prior art; whatever factual gaps there are in the reference are filled in by an unsupported assertion that the missing information is ***prima facie*** obvious (without a shred of support), or is supplied by the Examiner's omniscient knowledge that need not, and indeed can not and will not, be articulated. ***Fortunately, that is not the law.***

That the examiner can not just deem something obvious without support has been discussed above (***Ex parte Stern***, above on page 13). And as to combinations of references, the fundamental principle, as articulated by the Court of Appeals for the Federal Circuit in ***In re Gordon***, 221 USPQ 1125 (Fed. Cir. 1984), is that ***the prior art itself must suggest the combination of references***. In ***Gordon***, the Court rejected the idea that the prior art devices ***could be*** modified to produce the claimed device as a proper basis for an obviousness rejection, ***holding the combination is not proper unless the prior art actually suggests the desirability of such a modification***.

Note at this juncture that the Examiner here believes mere existence of an element of a combination automatically confers the motivation (the rejection says it "logically flows") and therefore she does not have to find the motivation within the references themselves. ***Wrong! That is not the law.***

In ***SmithKline Diagnostics, Inc. v. Helena Laboratories Corp.***, 8 USPQ2d 1468 (Fed. Cir. 1988), the Court held that to pick and chose elements from references to recreate the invention is ***not*** proper. And in ***Northern Telecom, Inc. v. Datapoint Corp.***, 15 USPQ2d 1531 (Fed. Cir. 1990), **cert. denied,** 498 U.S. 920 (1990), the Court held that

> "[i]t is insufficient that the prior art disclosed the components of the patented device, either separately or used in other combinations; there must be some teaching, suggestion, or incentive to make the combination made by the inventor." (Emphasis added).

These governing principles were applied by the Court in holding in error the obviousness

rejections in ***In re Bond***, 15 USPQ2d 1566 (Fed. Cir. 1990) and ***In re Mills***, 16 USPQ2d 1430 (Fed. Cir. 1990), among many cases. ***In re Mills*** specifically held that although the prior art device could be modified to run the way the applicant's device was claimed to run, "there must be a suggestion or motivation in the reference to do so." 16 USPQ2d 1430. Since there was none, the rejection was in error and was reversed. More recently, in ***Sensonics, Inc. v. Aerosonic Corp.***, 38 USPQ2d 1551 (Fed. Cir. 1996), the Court reiterated this principle, holding there was no teaching or suggestion in the prior art that would have led a person skilled in the art to select the specific structures and concepts and combine them in the manner of the invention of that case.

As a further principle, both the Courts and the Board of Appeal have long held that the suggestion for the combination in the references cannot come from the Applicant's Specification, see, for example, ***Ex parte Brack***, 134 USPQ 445 (POBA 1961). The reason is simple: **Applicant's Specification is not prior art.** ***Applicant's specification cannot be used as a parts list to search for disparate parts in the art, and then used as a blueprint to assemble the selected parts.*** The sources for the motive not only to select the parts, but also the direction for reassembling them into the claimed combination to obtain the desired result, must come from the references.

The above principles were not followed in this Office Action. For example, the Examiner fails to state "what was known in the art" on which is being relied (page 11). Just what was known that is being referred-to? Thus, "prima facie obvious" without support, is not the law. Nor is "logically flows" from mere existence of an isolated element in the prior art, the legal source for motivation to combine references.

What is most pernicious here is that the rejection has used Applicant's Specification to provide the motivation, then says, with disrespect, that the claims "would have been plainly obvious". Again, since Applicant's specification is not prior art, it cannot be used as either a parts list or a blueprint for the combination.

Finally,

> ***"Office personnel should indicate how rejections may be overcome and how problems may be resolved. A failure to follow this approach can lead to unnecessary delays in the prosecution of the application."***

Further:

> ***". . . every limitation in the claim must be considered. Office personnel may not dissect a claimed invention into discrete elements and then evaluate the ele-***

ments in isolation. Instead, the claim as a whole must be considered. See, e.g., Diamond v Diehr, 450 US at 188 –189, 209 USPQ at 9 (quoting from the case)."

Gosh, where are those quotes from? (From the Commissioner's Guidelines. MPEP 2106.)

The result is that the 103 rejections based on 6 references in combination are unsound and should be withdrawn.

CONCLUSION

Entry and consideration of the amendments is respectfully requested. The Restriction and Specification requirements should be withdrawn. The claims are not indefinite. It is Applicant's view that all 20 claims are now in condition for allowance and favourable action is urged.

An Interview to discuss the rejections and the references is respectfully requested.

Respectfully submitted,
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DATE: June 5, 2006

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End of Section 4.

End of Supplemental Response to November 16, 2005 Office Action.